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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Benny Pesach

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PRTSI

P.O. Box 16446

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EXAMINER

BERHANU, ETSUB D

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,600	Applicant(s) PESACH ET AL.	
	Examiner ETSUB D. BERHANU	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/06/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 1-62 are objected to because of the following informalities: claim 1 should be amended to replace the phrases “first, target, region” and “second, reference, region” with - - first target region - - and - - second reference region - -, respectively; claim 5 recites the phrase “dependence on ratios” while claim 6 recites the phrase “dependence on only ratios” – it is suggested that Applicant amend one of these phrases in order to provide consistency throughout the claims; the term “wavelength” in line 2 of claims 11, 18 and 37 should be amended to read - - wavelengths - -; it appears that claim 19 should be dependent upon claim 13 in order to provide proper antecedent basis for the recitations of first and second layers in the claims dependent upon claim 19. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 37 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation “the implant” in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 37 recites the limitation “choosing the wavelengths” in line 1. There is insufficient antecedent basis for this limitation in the claim as no prior method step of choosing wavelengths is recited. Claim 45 recites the limitation "the function" in lines 1-2. There is insufficient antecedent basis for this recitation in the claim.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In order for a method claim to qualify as statutory subject matter, the method claim must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. As neither of these requirements is met by method claims 1-62 of the current invention, claims 1-62 are considered to be non-statutory subject matter. To qualify as statutory subject matter, the claims should either positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or the claims should positively recite a transformation of the underlying subject matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 9-11 and 53-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Cliff'548 (cited by Applicant).

Figures 9 and 10 of Cliff'548 disclose a method of assaying glucose in a natural region of a body part (see ABSTRACT), the method comprising: illuminating a body part with at least one pulse of light at each of first and second wavelengths that stimulates photoacoustic waves in a first target region (chamber 15) and a second reference region (chamber 15a) of the body part (page 4, lines 8-20 and page 7, lines 25-

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27), wherein the reference region interfaces with the target region (transducer 14 which senses pressure is between chambers 15 and 15a and therefore the regions interface), and wherein the reference region has at least one known optoacoustic property (page 4, line 8 – page 5 line 3 indicates that experimentally derived constants are based on known optoacoustic properties of interfering components, the properties which are well known in the art); sensing pressure in the photoacoustic waves from the target and reference regions (page 7, lines 20-29); and using the sensed pressures and the at least one known optoacoustic property to assay glucose in the target region (page 6, lines 12-20). Regarding claims 53-56, Clift'578 discloses choosing a second reference wavelength that is targeted toward measuring the absorption and scattering measurements related to an interfering component (page 4, lines 8-20), wherein water is one of the interfering components (page 4, lines 23-25).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. While Caro'002 (USPN 5,348,002), Chou'821 (USPN 5,941,821), Oraevsky et al.'069 (USPN 6,405,069), Geva et al.'806 (USPN 6,466,806) and Lilienfeld-Toal'044 (USPN 6,484,044) each disclose a method of assaying glucose in a natural region of a body part by measuring photoacoustic waves arising from a photoacoustic effect, and Walker et al.'958 (USPN 6,690,958), Sfez et al.'653 (USPN 6,738,653) and Nagar et al.'288 (USPN 6,846,288) each disclose a method of assaying an analyte in a natural region of a body part by using a photoacoustic measurement, none of the prior art teaches or suggests, either alone or in combination, an artificial implant as a reference region or determining a concentration of an analyte based on a function having dependence on pressures only through ratios of pressures, in combination with the other claimed steps.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB